REMARKS/ARGUMENTS

Claims 1 to 30, as amended, are pending. Applicant has amended claims 3, 6, and 11. The amendments find full support in the original specification and claims. No new matter is presented. In view of the above amendments and following remarks, Applicant respectfully requests favorable reconsideration and a timely indication of allowance.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 3 to 6, and 11 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. First, the Examiner contends that claim 3 is indefinite for being grammatically indefinite. Applicants have amended to claim to clarify the typographical omission, thereby obviating this rejection.

Second, the Examiner objected to the omission of the phrase "to a temperature of" in claim 6. Applicants have amended this claim pursuant to the Examiner's suggestion, thereby obviating this rejections.

Finally, the Examiner objected to claim 11 for omitting the unit "wt/vol". Applicants have amended this claim to include the unit, thereby obviating this rejection.

For all these reasons, Applicant respectfully requests that the rejection under section 112, second paragraph, be withdrawn.

Rejection Under 35 U.S.C. § 102(b)

The Examiner rejected claims 1 to 5, 7 to 12, 14, 15 19, 20, 22 to 24, and 26 to 29 under 35 U.S.C. §102(b) as being

anticipated by WO 97/39761. Applicants respectfully traverse this rejection.

The Examiner suggests that publication WO 97/39761 describes each and every feature of the current method. A review of the specification and claims of the current application clearly refutes this contention. The claims of the current application are directed generally to:

> A process for enhancing the solubility of a blood protein solution comprising:
>
> (a) adding to a blood protein solution hydroxypropyl-α-cyclodextrin in an amount sufficient to form a stable complex with the protein; and
>
> (b) lyophilizing the solution of step (a) to form a lyophilized complex of the protein and hydroxypropyl-α-cyclodextrin without further heating of the formed complex

In short, the current application is directed to a process for enhancing the solubility of a blood protein that does not require the heating of the lyophilized blood complex. Indeed, in the specification Applicants recite that "[i]f desired, the blood protein can be subjected to one or more viral inactivation steps prior to lyophilization, and preferably prior to complexing with the HPαCD." (Specification, page 2, lines 25 to 26, underlining added for emphasis.) It has been surprisingly discovered that heating the blood protein prior to complexing can adequately eliminate any viral contaminants, while avoiding such heating after complexing can increase the potency of the blood protein once reconstituted.

In contrast, the reference cited by the Examiner is explicitly directed to a process for "viral inactivation", in which "[t]he lyophilized blood protein/cyclodextrin complex is then heated to a temperature for a time sufficient to inactivate any viral contaminants, preferably to a temperature of at least about 60 ºC . . . ." (Specification, page 1, lines 35 to 37.) Nowhere, do the authors of the WO 97/39761 reference ever suggest a process which does not require the further heating of the blood protein complex to inactivate any viral contaminants.

Accordingly, Applicants submit that the disclosure of the WO 97/39761 cannot be said to anticipate the claims of the current application.

Rejection Under 35 U.S.C. § 103

The Examiner rejected claims 6,13, 16 to 18, 21, 25,and 30 under 35 U.S.C. § 103(a) as allegedly unpatentable over WO 97/39761. Applicant respectfully traverses this rejection.

As discussed above, all of the independent claims recite a process for enhancing the solubility of a blood protein solution comprising: (a) adding to a blood protein solution hydroxypropyl-α-cyclodextrin in an amount sufficient to form a stable complex with the protein; and (b) lyophilizing the solution of step (a) to form a lyophilized complex of the protein and hydroxypropyl-α-cyclodextrin, <u>without further heating of the formed complex</u>. Such a method is not taught by the cited reference.

The WO 97/39761 reference is directed to a method of inactiviting viruses in blood proteins comprising heating the protein complex to a temperature of at least 60 °C. Indeed, in

the description of the prior art, the Examiner acknowledges that the reference teaches such a heating. In short, nothing in the WO 97/39761 reference teaches or suggests using cyclodextrins to stabilize blood proteins, much less using hydroxypropyl-α-cyclodextrin to do so, without further heating of the blood protein/stabilizer complex.

For all these reasons, the cited reference does not render obvious the claimed invention. Applicant therefore respectfully requests that the rejection under section 103 be withdrawn.

In view of the foregoing amendments and remarks, Applicant respectfully submits that pending claims 1 to 30 are in condition for allowance, and a timely indication of allowance is respectfully requested. If there are any remaining issues that can be addressed by telephone, Applicant invites the Examiner to contact the undersigned at the number indicated below.

Respectfully submitted,
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